IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

JOURNEY MEDICAL CORPORATION, Plaintiff, v. PADAGIS ISRAEL PHARMACEUTICALS LTD. Defendant.	))))))))))	C.A. No. _____ **ANDA CASE**

COMPLAINT

Plaintiff Journey Medical Corporation ("Plaintiff"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Defendant Padagis Israel Pharmaceuticals Ltd. ("Padagis") of an Abbreviated New Drug Application ("ANDA") No. 217148 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell Minocycline Topical Foam, 1.5%, (Padagis's ANDA Product) a generic version of Journey Medical Corporation's Zilxi® product, prior to the expiration of U.S. Patent Nos. 8,865,139 ("the '139 patent"); 8,945,516 ("the '516 patent"); 8,992,896 ("the '896 patent"); 9,675,700 ("the '700 patent"); 10,213,512 ("the '512 patent"); 10,265,404 ("the '404 patent"); 10,322,186 ("the '186 patent"); and 10,946,101 ("the '101 patent") (collectively, "the Asserted Patents"). Padagis notified Plaintiff that it had submitted this ANDA by a letter dated April 6, 2022 ("the Notice

Letter"). Upon information and belief, Padagis's ANDA Product will be marketed as a generic competing product to Zilxi®, a product marketed by Plaintiff for the treatment of rosacea.

PARTIES

2. Plaintiff Journey Medical Corporation is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and place of businesses at 9237 East Via De Ventura Blvd., Suite 105 Scottsdale, Arizona 85258.

3. Upon information and belief, Defendant Padagis is a corporation organized and existing under the laws of Israel, having its principal place of business at 1 Rakefet St., Shoham, Israel 6085001. On information and belief, Padagis is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries.

JURISDICTION AND VENUE

4. This court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. This court has personal jurisdiction over Padagis. Upon information and belief, Padagis is engaged in developing, manufacturing, marketing, importing, selling, and distributing a broad range of generic pharmaceutical products throughout the United States, including in Delaware. Upon information and belief, a substantial number of these products are marketed throughout the United States, including in the State of Delaware. Upon information and belief, Padagis purposefully operates its manufacturing, marketing, sales, and distribution infrastructure in the United States either itself or via corporate parents, subsidiaries, and affiliates as a vertically integrated company.

6. Alternatively, if the exercise of personal jurisdiction over Padagis in this Court is not held to be proper, then, upon information and belief, Padagis is not subject to jurisdiction in any state's courts of general jurisdiction, and therefore personal jurisdiction over Padagis in this Court is proper pursuant to Fed. R. Civ. P. 4(k)(2).

7. Upon information and belief, Padagis has been sued in this judicial district without challenging personal jurisdiction and has availed themselves of the legal protections of the State of Delaware by filing claims or counterclaims affirmatively seeking relief in other prior actions in this Court, including *Journey Medical Corporation et al v. Padagis US LLC, f/k/a Perrigo Pharma International DAC*, C.A. No. 1-20-cv-01413-CFC and *Anacor Pharmaceuticals, Inc. et al v. Padagis Israel Pharmaceuticals, Ltd. f/k/a Perrigo Israel Pharmaceuticals, Ltd. et al,* C.A. No. 1:21-cv-01351-CFC.

8. Upon information and belief, Padagis regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

9. Upon information and belief, Padagis has sought approval in ANDA No. 217148 to distribute Padagis' ANDA Product in the United States, including in Delaware and will do so upon approval of ANDA No. 217148. The filing of ANDA No. 217148 is therefore tightly tied, in purpose and planned effect, to the deliberate making of sales in Delaware, and reliably indicates that Padagis plans to engage in the marketing of Padagis's ANDA Product in this State.

10. Upon information and belief, with knowledge of the processes described in the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b) and the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch Waxman Act"), Padagis sent

its Notice Letter to Journey Medical Corporation and alleged in the Notice Letter the invalidity, unenforceability, and/or non-infringement of the Asserted Patents. Upon information and belief, the Padagis deliberately challenged Plaintiff's patent rights with the Notice Letter and knew when it did so that it was triggering a forty-five-day period for Plaintiffs to bring an action for patent infringement under the FDCA.

11. Because Zilxi® is marketed, sold, and distributed throughout the United States, including in the State of Delaware, the injury, and consequences of Padagis's filing of ANDA No. 217148, challenging Plaintiff's patent rights, are suffered in Delaware. Upon information and belief, Padagis knew that it was deliberately challenging intellectual property held in Delaware and that the effects of any successful challenge of the Asserted Patents would be felt by Plaintiff in Delaware.

12. Upon information and belief, if the ANDA No. 217148 is approved, Padagis will directly or indirectly market and/or sell Padagis's ANDA Product within the United States, including in Delaware, consistent with Padagis's practices for the marketing and distribution of other pharmaceutical products on its own or through its affiliates. Upon information and belief, Padagis and/or its affiliates regularly do business in Delaware, and their practices with other pharmaceutical products have involved the distribution of Padagis products, directly or indirectly, throughout the United States, including in Delaware. Upon information and belief, Padagis's pharmaceutical products are used and/or consumed within and throughout the United States, including Delaware.

13. Upon information and belief, Padagis and its affiliates derive substantial revenue from pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Padagis or its affiliates and/or for which Padagis is the named applicant on

approved ANDAs. Upon information and belief, various products for which Padagis, or its affiliates, is the named applicant on approved ANDAs are available at pharmacies in Delaware.

14. Upon information and belief, if ANDA No. 217148 is approved, Padagis's ANDA Product, under the direction and control of physicians practicing in Delaware, will be administered to patients in Delaware. These activities, as well as Padagis's marketing, selling, and/or distributing of Padagis's ANDA Product, would have a substantial effect within Delaware and would constitute infringement of the Asserted Patents in the event that Padagis's ANDA Product is approved before the Asserted Patents expire.

15. For the reasons described above, among others, the filing of ANDA No. 217148 was suit-related conduct with a substantial connection to Delaware and this District, the exercise of personal jurisdiction over Padagis does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over Padagis.

16. Upon information and belief and based on the foregoing, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Padagis is a foreign entity incorporated in Israel and may be sued in any judicial district in the United States.

BACKGROUND

17. Zilxi® (minocycline hydrochloride) is indicated for the treatment of inflammatory lesions of rosacea in adults.

18. Journey Medical Corporation is the holder of approved NDA No. 213690 for Zilxi®. Zilxi® is manufactured by Journey Medical Corporation and is sold in in the United States pursuant to NDA No. 213690.

19. The '139 patent, titled "Topical Tetracycline Compositions" was duly and legally issued on October 21, 2014. A copy of the '139 patent is attached as Exhibit A.

20. Journey Medical Corporation is the assignee of the ’139 patent.

21. An actual case or controversy exists between Plaintiff and Padagis with respect to infringement of the ’139 patent.

22. The ’516 patent, titled “Surfactant-Free Water-free Foamable Compositions, Breakable Foams and Gels and Their Uses” was duly and legally issued on February 3, 2015. A copy of the ’516 patent is attached as Exhibit B.

23. Journey Medical Corporation is the assignee of the ’516 patent.

24. An actual case or controversy exists between Plaintiff and Padagis with respect to infringement of the ’516 patent.

25. The ’896 patent, titled “Topical Tetracycline Compositions” was duly and legally issued on March 31, 2015. A copy of the ’896 patent is attached as Exhibit C.

26. Journey Medical Corporation is the assignee of the ’896 patent.

27. An actual case or controversy exists between Plaintiff and Padagis with respect to infringement of the ’896 patent.

28. The ’700 patent, titled “Topical Tetracycline Compositions” was duly and legally issued on June 13, 2017. A copy of the ’700 patent is attached as Exhibit D.

29. Journey Medical Corporation is the assignee of the ’700 patent.

30. An actual case or controversy exists between Plaintiff and Padagis with respect to infringement of the ’700 patent.

31. The ’512 patent, titled “Topical Tetracycline Compositions” was duly and legally issued on February 26, 2019. A copy of the ’512 patent is attached as Exhibit E.

32. Journey Medical Corporation is the assignee of the ’512 patent.

33. An actual case or controversy exists between Plaintiff and Padagis with respect to infringement of the '512 patent.

34. The '404 patent, titled "Compositions, Gels and Foams with Rheology Modulators and uses Thereof" was duly and legally issued on April 23, 2019. A copy of the '404 patent is attached as Exhibit F.

35. Journey Medical Corporation is the assignee of the '404 patent.

36. An actual case or controversy exists between Plaintiff and Padagis with respect to infringement of the '404 patent.

37. The '186 patent, titled "Topical Tetracycline Compositions" was duly and legally issued on June 18, 2019. A copy of the '186 patent is attached as Exhibit G.

38. Journey Medical Corporation is the assignee of the '186 patent.

39. An actual case or controversy exists between Plaintiff and Padagis with respect to infringement of the '186 patent.

40. The '101 patent, titled "Surfactant-Free Water-free Foamable Compositions, Breakable Foams and Gels and Their Uses" was duly and legally issued on March 16, 2021. A copy of the '101 patent is attached as Exhibit H.

41. Journey Medical Corporation is the assignee of the '101 patent.

42. An actual case or controversy exists between Plaintiff and Padagis with respect to infringement of the '101 patent.

43. Padagis sent its Notice Letter Journey Medical Corporation on April 6, 2022. This action is being filed within 45 days of the date of Padagis's Notice Letter.

COUNT I
(Infringement of the '139 Patent Under 35 U.S.C. § 271(e)(2))

44. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

45. Claim 1 of the '139 patent claims: "A composition comprising a carrier comprising: a) about 60% to 99% by weight of the composition of at least one hydrophobic oil; and b) at least one viscosity-modifying agent that is a combination comprising (i) at least one fatty alcohol and at least one wax; (ii) at least one fatty acid and at least one wax; or (iii) at least one fatty alcohol, at least one fatty acid, and at least one wax; wherein the wax is selected from the group consisting of a plant wax, an animal wax, a petroleum derived wax, and a vegetable wax; or wherein the wax is selected from the group consisting of an albacer wax, an atlasene wax, a cardis wax, a ceramid, an alkyl-substituted aromatic compound, a naphthene-substituted aromatic compound, a beeswax, a BASF wax, a carnauba wax, a chinese wax, a cotton wax, a bayberry wax, a carnauba wax, a castor wax, a cuban palm wax, a duroxon wax, an esparto wax, a fat wax, a flax wax, a fischer-tropsch wax, a fir wax, a flexo wax a flower wax, glyco waxes, a japan wax, a jojoba oil, a lanolin wax, a palm wax, a rice bran wax, a rice-oil wax, a shellac wax, a soy wax, an ucuhuba wax, a hydrogenated oil, a hydrogenated castor oil, a hydrogenated cottonseed oil, a hydrogenated jojoba oil, a mink wax, a mixture of saturated n- and isoalkanes, a montan wax, a naphthene, an ouricury wax, an oxazoline wax, an ozokerite, a paraffin wax, a paraffin 58-62° C. wax, paraffin 51-53° C. wax, paraffin 42-44° C. wax, a polyethylene wax, a PEG-6 beeswax, a polymekon wax, a retamo wax, a rezo wax, a sandy wax, a spent grain wax, a stearyl dimethicone, a sugarcane wax, a synthetic mineral wax, and mixtures and any two or more thereof; the carrier being otherwise free of or containing less than 0.1% by weight of a surfactant; a tetracycline antibiotic, at least part of which is suspended in the composition; and a liquefied or compressed gas propellant; wherein the composition is waterless; and wherein when packaged in an aerosol container and pressurized with

a liquefied or compressed gas propellant, the composition affords upon release from the container a foam that breaks upon application of shear force."

46. Upon information and belief, Padagis's ANDA product is covered by one or more claims of the '139 patent, including at least claim 1.

47. Upon information and belief, the use of Padagis's ANDA Product and its use in accordance with and as directed by Padagis's proposed labeling for that product will infringe one or more claims of the '139 patent, including at least claim 1, either literally or under the doctrine of equivalents.

48. Upon information and belief, Padagis filed as part of ANDA No. 217148 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. §355(b)(2)(A)(iv), asserting that the claims of the '139 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Padagis's ANDA Product.

49. The purpose of filing ANDA No. 217148 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '139 patent.

50. Padagis's submission of ANDA No. 217148 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '139 patent is an act of infringement of the '139 patent under 35 U.S.C. § 271(e)(2)(A).

51. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto, i.e., prior to the expiration of the '139 patent.

52. Upon information and belief, Padagis has knowledge of the claims of the '139 patent at least because the '139 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Journey's Zilxi® drug product. Notwithstanding this knowledge, Padagis continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto.

53. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '139 patent, including at least claim 40, when ANDA No. 217148 and any amendments thereto are approved and will do so with specific intent to induce infringement of the '139 patent under 35 U.S.C. § 271(b). Further upon information and belief, Padagis plans and intends to, and will, do so immediately and imminently upon approval.

54. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '139 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '139 patent, including at least claim 40, under 35 U.S.C. § 271(c) immediately and imminently upon approval of ANDA No. 217148 and any amendments thereto.

55. The foregoing actions by Padagis constitute and/or will constitute infringement of the '139 patent, active inducement of infringement of the '139 patent, and contribution to the infringement by others of the '139 patent either literally or under the doctrine of equivalents.

56. Unless Padagis is enjoined from infringing the '139 patent, actively inducing infringement of the '139 patent, and contributing to the infringement by others of the '139 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

COUNT II
(Infringement of the '516 Patent Under 35 U.S.C. § 271(e)(2))

57. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

58. Claim 1 of the '516 patent covers "[a] surfactant free, flowable foamable composition comprising: a carrier comprising: a) about 60% to about 95% by weight of the carrier of a hydrophobic solvent, wherein the hydrophobic solvent is an oil; and b) an oleaginous foamer complex comprising: (1) about 0.1% to about 20% by weight of the carrier of at least one fatty alcohol, wherein the fatty alcohol has a carbon chain length of 14 to 22 carbons; and (2) about 0.1% to about 20% by weight of the carrier of at least one fatty acid, at least one wax, at least one shea butter, or mixtures of two or more thereof, wherein the fatty acid has a carbon chain length of 12 to 28 carbons, and the wax is selected from the group consisting of a beeswax, a hydrogenated castor oil, a paraffin wax, a wax that is solid at room temperature, and mixtures of two or more thereof; and a liquefied or compressed gas propellant; wherein the composition comprises 15% or less than 15% of petrolatum by weight of the carrier; wherein the composition is essentially waterless; wherein the composition is free of polymeric agent; and wherein the ratio of carrier to propellant is from about 100:3 to about 100:30; and wherein upon dispensing, the flowable foamable composition forms a breakable foam that breaks easily upon application of shear force."

59. Upon information and belief, Padagis's ANDA product is covered by one or more claims of the '516 patent, including at least claim 1.

60. Upon information and belief, the use of Padagis's ANDA Product and its use in accordance with and as directed by Padagis's proposed labeling for that product will infringe one

or more claims of the '516 patent, including at least claim 1, either literally or under the doctrine of equivalents.

61. Upon information and belief, Padagis filed as part of ANDA No. 217148 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. §355(b)(2)(A)(iv), asserting that the claims of the '516 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Padagis's ANDA Product.

62. The purpose of filing ANDA No. 217148 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '516 patent.

63. Padagis's submission of ANDA No. 217148 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '516 patent is an act of infringement of the '516 patent under 35 U.S.C. § 271(e)(2)(A).

64. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto, i.e., prior to the expiration of the '516 patent.

65. Upon information and belief, Padagis has knowledge of the claims of the '516 patent at least because the '516 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Journey's Zilxi® drug product. Notwithstanding this knowledge, Padagis continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's

ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto.

66. The foregoing actions by Padagis constitute and/or will constitute infringement of the '516 patent either literally or under the doctrine of equivalents.

67. Unless Padagis is enjoined from infringing the '516 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

COUNT III
(Infringement of the '896 Patent Under 35 U.S.C. § 271(e)(2))

68. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

69. Claim 1 of the '896 patent covers "[a] composition comprising a carrier comprising: a) about 60% to 99% by weight of the composition of at least one hydrophobic oil; and b) at least one viscosity-modifying agent that is a combination comprising (i) at least one fatty alcohol and at least one wax; (ii) at least one fatty acid and at least one wax; or (iii) at least one fatty alcohol, at least one fatty acid, and at least one wax; wherein the composition does not contain one or more of aminocycline incompatible substance selected from the group consisting of dimethyl sulfoxide (DMSO), dimethylformamide (DMF), acetonitrile, acetone, methyl ethyl ketone, 1,4-dioxane, tetrahydrofuran (THF), N-methylpyrrolidone, pyridine, piperidine, dimethylformamide, N-methyl-2-pyrrolidone and 1-methyl-2-pyrrolidinone), azone (1-dodecylazacycloheptan-2-one), dimethyl isosorbide, glycerin, ethanol, propylene glycol, butylene glycol, PEG 200, hexylene glycol, PEG 400, diethylene glycol monoethyl ether, pomegranate seed oil, and isostearic acid, and ethocel; the carrier being otherwise free of or containing less than 0.1% by weight of a surfactant; a tetracycline antibiotic; and wherein the composition is waterless; and wherein when packaged in an aerosol container and pressurized with a propellant, the composition affords upon release from the container a foam that breaks upon application of shear force."

70. Upon information and belief, Padagis's ANDA product is covered by one or more claims of the '896 patent, including at least claim 1.

71. Upon information and belief, the use of Padagis's ANDA Product and its use in accordance with and as directed by Padagis's proposed labeling for that product will infringe one or more claims of the '896 patent, including at least claim 1, either literally or under the doctrine of equivalents.

72. Upon information and belief, Padagis filed as part of ANDA No. 217148 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. §355(b)(2)(A)(iv), asserting that the claims of the '896 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Padagis's ANDA Product.

73. The purpose of filing ANDA No. 217148 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '896 patent.

74. Padagis's submission of ANDA No. 217148 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '896 patent is an act of infringement of the '896 patent under 35 U.S.C. § 271(e)(2)(A).

75. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto, i.e., prior to the expiration of the '896 patent.

76. Upon information and belief, Padagis has knowledge of the claims of the '896 patent at least because the '896 patent is listed in the FDA's *Orange Book: Approved Drug*

Products with Therapeutic Equivalence Evaluations for Journey's Zilxi® drug product. Notwithstanding this knowledge, Padagis continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto.

77. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '896 patent, including at least claim 49, when ANDA No. 217148 and any amendments thereto are approved and will do so with specific intent to induce infringement of the '896 patent under 35 U.S.C. § 271(b). Further upon information and belief, Padagis plans and intends to, and will, do so immediately and imminently upon approval.

78. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '896 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '896 patent including at least claim 49, under 35 U.S.C. § 271(c) immediately and imminently upon approval of ANDA No. 217148 and any amendments thereto.

79. The foregoing actions by Padagis constitute and/or will constitute infringement of the '896 patent, active inducement of infringement of the '896 patent, and contribution to the infringement by others of the '896 patent either literally or under the doctrine of equivalents.

80. Unless Padagis is enjoined from infringing the '896 patent, actively inducing infringement of the '896 patent, and contributing to the infringement by others of the '896 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

COUNT IV
(Infringement of the '700 Patent Under 35 U.S.C. § 271(e)(2))

81. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

82. Claim 1 of the '700 patent covers "[a] waterless composition comprising a tetracycline antibiotic and a carrier, the carrier comprising: a) at least one hydrophobic oil; and b) an agent comprising (i) at least one fatty alcohol and at least one wax; (ii) at least one fatty acid and at least one wax; (iii) at least one fatty alcohol, at least one fatty acid, and at least one wax; (iv) a wax comprising a hydrogenated oil; or (v) a combination of two or more waxes; wherein the composition does not contain one or more minocycline incompatible substance selected from the group consisting of dimethyl sulfoxide (DMSO), dimethylformamide (DMF), acetonitrile, acetone, methyl ethyl ketone, 1,4-dioxane, tetrahydrofuran (THF), N-methylpyrrolidone, pyridine, piperidine, N-methyl-2-pyrrolidone and 1-methyl-2-pyrrolidinone), azone (1-dodecylazacycloheptan-2-one), dimethyl isosorbide, glycerin, ethanol, propylene glycol, butylene glycol, PEG 200, hexylene glycol, PEG 400, diethylene glycol monoethyl ether, pomegranate seed oil, isostearic acid, and ethocel; and wherein the composition does not contain a polyol and/or polyethylene glycol."

83. Upon information and belief, Padagis's ANDA product is covered by one or more claims of the '700 patent, including at least claim 1.

84. Upon information and belief, the use of Padagis's ANDA Product and its use in accordance with and as directed by Padagis's proposed labeling for that product will infringe one or more claims of the '700 patent, including at least claim 1, either literally or under the doctrine of equivalents.

85. Upon information and belief, Padagis filed as part of ANDA No. 217148 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C.

§355(b)(2)(A)(iv), asserting that the claims of the '700 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Padagis's ANDA Product.

86. The purpose of filing ANDA No. 217148 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '700 patent.

87. Padagis's submission of ANDA No. 217148 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '700 patent is an act of infringement of the '700 patent under 35 U.S.C. § 271(e)(2)(A).

88. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto, i.e., prior to the expiration of the '700 patent.

89. Upon information and belief, Padagis has knowledge of the claims of the '700 patent at least because the '700 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Journey's Zilxi® drug product. Notwithstanding this knowledge, Padagis continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto.

90. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '700 patent, including at least claim 59, when ANDA No. 217148 and any amendments thereto are approved and will do so with specific intent to induce infringement of the

'700 patent under 35 U.S.C. § 271(b). Further upon information and belief, Padagis plans and intends to, and will, do so immediately and imminently upon approval.

91. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '700 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '700 patent including at least claim 59, under 35 U.S.C. § 271(c) immediately and imminently upon approval of ANDA No. 217148 and any amendments thereto.

92. The foregoing actions by Padagis constitute and/or will constitute infringement of the '700 patent, active inducement of infringement of the '700 patent, and contribution to the infringement by others of the '700 patent either literally or under the doctrine of equivalents.

93. Unless Padagis is enjoined from infringing the '700 patent, actively inducing infringement of the '700 patent, and contributing to the infringement by others of the '700 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

COUNT V
(Infringement of the '512 Patent Under 35 U.S.C. § 271(e)(2))

94. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

95. Claim 1 of the '512 patent covers "[a] foamable, waterless, surfactant-free composition comprising a carrier and a liquefied or compressed gas propellant, the carrier comprising: a) a tetracycline antibiotic; b) a combination of two or more hydrophobic oils, wherein at least one of the hydrophobic oils is a light mineral oil and the other hydrophobic oil comprises a heavy mineral oil, soybean oil, and/or coconut oil; c) a combination of two or more fatty alcohols, wherein at least one of the fatty alcohols is stearyl alcohol; d) optionally stearic acid; and e) wherein the carrier comprises at least one wax; wherein the hydrophobic oils are present at between

about 70% and 95% by weight of the carrier; wherein ratio of the fatty alcohols to stearic acid, if present, is between about 4:1 and 1:4; wherein the fatty alcohols and the wax are present at a ratio between about 4:1 and 3:2; wherein the ratio of the carrier to the propellant is between about 100:1 and about 100:25; and wherein upon release from an aerosol container, the composition forms a foam."

96. Upon information and belief, Padagis's ANDA product is covered by one or more claims of the '512 patent, including at least claim 1.

97. Upon information and belief, the use of Padagis's ANDA Product and its use in accordance with and as directed by Padagis's proposed labeling for that product will infringe one or more claims of the '512 patent, including at least claim 1, either literally or under the doctrine of equivalents.

98. Upon information and belief, Padagis filed as part of ANDA No. 217148 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. §355(b)(2)(A)(iv), asserting that the claims of the '512 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Padagis's ANDA Product.

99. The purpose of filing ANDA No. 217148 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '512 patent.

100. Padagis's submission of ANDA No. 217148 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '512 patent is an act of infringement of the '512 patent under 35 U.S.C. § 271(e)(2)(A).

101. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto, i.e., prior to the expiration of the '512 patent.

102. Upon information and belief, Padagis has knowledge of the claims of the '512 patent at least because the '512 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Journey's Zilxi® drug product. Notwithstanding this knowledge, Padagis continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto.

103. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '512 patent, including at least claim 32, when ANDA No. 217148 and any amendments thereto are approved and will do so with specific intent to induce infringement of the '512 patent under 35 U.S.C. § 271(b). Further upon information and belief, Padagis plans and intends to, and will, do so immediately and imminently upon approval.

104. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '512 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '512 patent, including at least claim 32, under 35 U.S.C. § 271(c), immediately and imminently upon approval of ANDA No. 217148 and any amendments thereto.

105. The foregoing actions by Padagis constitute and/or will constitute infringement of the '512 patent, active inducement of infringement of the '512 patent, and contribution to the infringement by others of the '512 patent either literally or under the doctrine of equivalents.

106. Unless Padagis is enjoined from infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

COUNT VI
(Infringement of the '404 Patent Under 35 U.S.C. § 271(e)(2))

107. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

108. Claim 1 of the '404 patent covers "[a]n oleaginous foam composition comprising: a) a combination of at least one fatty alcohol and at least one wax; or a combination of at least one fatty alcohol, at least one fatty acid, and at least one wax; b) at least one hydrophobic solvent; and c) a minocycline at a concentration between about 1% and about 4% by weight of the composition; wherein the composition is free of surfactant; wherein the composition is essentially waterless; wherein the ratio of (1) fatty alcohol to wax or (2) fatty alcohol and fatty acid to wax is between about 1:3 and about 3:1; and wherein the wax comprises a mixture of beeswax and hydrogenated castor oil."

109. Upon information and belief, Padagis's ANDA product is covered by one or more claims of the '404 patent, including at least claim 1.

110. Upon information and belief, the use of Padagis's ANDA Product and its use in accordance with and as directed by Padagis's proposed labeling for that product will infringe one or more claims of the '404 patent, including at least claim 1, either literally or under the doctrine of equivalents.

111. Upon information and belief, Padagis filed as part of ANDA No. 217148 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. §355(b)(2)(A)(iv), asserting that the claims of the '404 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Padagis's ANDA Product.

112. The purpose of filing ANDA No. 217148 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '404 patent.

113. Padagis's submission of ANDA No. 217148 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '404 patent is an act of infringement of the '404 patent under 35 U.S.C. § 271(e)(2)(A).

114. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto, i.e., prior to the expiration of the '404 patent.

115. Upon information and belief, Padagis has knowledge of the claims of the '404 patent at least because the '404 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Journey's Zilxi® drug product. Notwithstanding this knowledge, Padagis continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto.

116. The foregoing actions by Padagis constitute and/or will constitute infringement of the '404 patent, either literally or under the doctrine of equivalents.

117. Unless Padagis is enjoined from infringing the '404 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

COUNT VII
(Infringement of the '186 Patent Under 35 U.S.C. § 271(e)(2))

118. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

119. Claim 1 of the '186 patent covers "[a] method of treating rosacea, comprising administering a waterless foam composition comprising a minocycline and a foamable carrier, the carrier comprising: a) at least one hydrophobic oil; and b) an agent comprising (i) at least one fatty alcohol and at least one wax; (ii) at least one fatty acid and at least one wax; (iii) at least one fatty alcohol, at least one fatty acid, and at least one wax; (iv) a wax comprising a hydrogenated oil; or (v) a combination of two or more waxes; wherein the composition does not contain one or more minocycline incompatible substance selected from the group consisting of dimethyl sulfoxide (DMSO), dimethylformamide (DMF), acetonitrile, acetone, methyl ethyl ketone, 1,4-dioxane, tetrahydrofuran (THF), N-methylpyrrolidone, pyridine, piperidine, N-methyl-2-pyrrolidone and 1-methyl-2-pyrrolidinone), azone (1-dodecylazacycloheptan-2-one), dimethyl isosorbide, glycerin, ethanol, propylene glycol, butylene glycol, PEG 200, hexylene glycol, PEG 400, diethylene glycol monoethyl ether, pomegranate seed oil, isostearic acid, and ethylcellulose; wherein the composition does not contain a surfactant; and wherein the composition does not contain a polyol."

120. Upon information and belief, Padagis's ANDA product is covered by one or more claims of the '186 patent, including at least claim 1.

121. Upon information and belief, the use of Padagis's ANDA Product and its use in accordance with and as directed by Padagis's proposed labeling for that product will infringe one

or more claims of the '186 patent, including at least claim 1, either literally or under the doctrine of equivalents.

122. Upon information and belief, Padagis filed as part of ANDA No. 217148 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. §355(b)(2)(A)(iv), asserting that the claims of the '186 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Padagis's ANDA Product.

123. The purpose of filing ANDA No. 217148 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '186 patent.

124. Padagis's submission of ANDA No. 217148 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '186 patent is an act of infringement of the '186 patent under 35 U.S.C. § 271(e)(2)(A).

125. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto, i.e., prior to the expiration of the '186 patent.

126. Upon information and belief, Padagis has knowledge of the claims of the '186 patent at least because the '186 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Journey's Zilxi® drug product. Notwithstanding this knowledge, Padagis continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's

ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto.

127. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '186 patent, including at least claim 1, when ANDA No. 217148 and any amendments thereto are approved and will do so with specific intent to induce infringement of the '186 patent under 35 U.S.C. § 271(b). Further upon information and belief, Padagis plans and intends to, and will, do so immediately and imminently upon approval.

128. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '186 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '186 patent, including at least claim 1, under 35 U.S.C. § 271(c) immediately and imminently upon approval of ANDA No. 217148 and any amendments thereto.

129. The foregoing actions by Padagis constitute and/or will constitute infringement of the '186 patent, active inducement of infringement of the '186 patent, and contribution to the infringement by others of the '186 patent either literally or under the doctrine of equivalents.

130. Unless Padagis is enjoined from infringing the '186 patent, actively inducing infringement of the '186 patent, and contributing to the infringement by others of the '186 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

COUNT VIII
(Infringement of the '101 Patent Under 35 U.S.C. § 271(e)(2))

131. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

132. Claim 1 of the '101 patent covers "[a] method of treating rosacea, consisting of administering a surfactant free foam composition, obtained from a foamable composition

dispensed from a container, to a subject in need thereof, wherein the foamable composition consists of: i) a carrier consisting of: a) about 60% to about 95% by weight of the carrier of a hydrophobic solvent; b) about 0.1% to about 20% by weight of the carrier of at least one fatty alcohol, wherein the fatty alcohol has a carbon chain length of 14 to 22 carbons; c) about 0.1% to about 20% by weight of the carrier of at least one fatty acid, at least one wax, at least one shea butter, or mixtures of two or more thereof, wherein the fatty acid has a carbon chain length of 12 to 28 carbons, and the wax is selected from the group consisting of a beeswax, a hydrogenated castor oil, a paraffin wax, a wax that is solid at room temperature, and a mixture of any two or more thereof; and d) one active agent, wherein the one active agent is minocycline or a salt thereof; and ii) a liquefied or compressed gas propellant; wherein the foamable composition comprises 15% or less of petrolatum by weight of the carrier; wherein the foamable composition is essentially waterless; wherein the foamable composition is free of polymeric agent; wherein, upon dispensing, the foamable composition forms a foam; and wherein the subject in need thereof has rosacea."

133. Upon information and belief, Padagis's ANDA product is covered by one or more claims of the '101 patent, including at least claim 1.

134. Upon information and belief, the use of Padagis's ANDA Product and its use in accordance with and as directed by Padagis's proposed labeling for that product will infringe one or more claims of the '101 patent, including at least claim 1, either literally or under the doctrine of equivalents.

135. Upon information and belief, Padagis filed as part of ANDA No. 217148 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. §355(b)(2)(A)(iv), asserting that the claims of the '101 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Padagis's ANDA Product.

136. The purpose of filing ANDA No. 217148 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '101 patent.

137. Padagis's submission of ANDA No. 217148 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Padagis's ANDA Product prior to the expiration of the '101 patent is an act of infringement of the '101 patent under 35 U.S.C. § 271(e)(2)(A).

138. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto, i.e., prior to the expiration of the '101 patent.

139. Upon information and belief, Padagis has knowledge of the claims of the '101 patent at least because the '101 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Journey's Zilxi® drug product. Notwithstanding this knowledge, Padagis continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217148 and any amendments thereto.

140. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '101 patent, including at least claim 1, when ANDA No. 217148 and any amendments thereto are approved and will do so with specific intent to induce infringement of the '101 patent under 35 U.S.C. § 271(b). Further upon information and belief, Padagis plans and intends to, and will, do so immediately and imminently upon approval.

141. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '101 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '101 patent including at least claim 1, under 35 U.S.C. § 271(c) immediately and imminently upon approval of ANDA No. 217148 and any amendments thereto.

142. The foregoing actions by Padagis constitute and/or will constitute infringement of the '101 patent, active inducement of infringement of the '101 patent, and contribution to the infringement by others of the '101 patent either literally or under the doctrine of equivalents.

143. Unless Padagis is enjoined from infringing the '101 patent, actively inducing infringement of the '101 patent, and contributing to the infringement by others of the '101 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

COUNT IX
(Declaratory Judgment of Patent Infringement of the '139 Patent Under 35 U.S.C. § 271(a), (b), and/or (c))

144. Plaintiff realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

145. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

146. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Padagis's ANDA Product, if approved by the FDA, will infringe literally and/or under the doctrine of equivalents one or more claims of the '139 patent under 35 U.S.C. § 271(a), in violation of Plaintiff's patent rights.

147. Upon information and belief, Padagis has knowledge of the '139 patent and has filed ANDA No. 217148 seeking authorization to commercially manufacture, use, offer for sale, and sell Padagis's ANDA Product in the United States. Upon information and belief, if the FDA approves ANDA No. 217148, physicians, health care providers, and/or patients will use Padagis's ANDA Product in accordance with the instructions and/or label provided by Padagis and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '139 patent under 35 U.S.C. § 271(a), in violation of Plaintiff's patent rights.

148. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Padagis's ANDA Product so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '139 patent, including at least claim 40, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiff's patent rights.

149. Upon information and belief, Padagis knows and intends that physicians, health care providers, and/or patients will use Padagis's ANDA Product in accordance with the instructions and/or label provided by the '139 patent, including at least claim 40, with the requisite intent under 35 U.S.C. § 271(b).

150. Upon information and belief, if the FDA approves ANDA No. 217148, Padagis will sell or offer to sell Padagis's ANDA Product specifically labeled for use in practicing one or more claims of the '139 patent, including at least claim 40, wherein Padagis's ANDA Product is a material part of the invention claimed in the '139 patent, wherein Padagis knows that physicians will prescribe and patients will use Padagis's ANDA Product for practicing one or more claims in the '139 patent, and wherein Padagis's ANDA Product is not a staple article or commodity of

commerce suitable for substantial noninfringing use. Upon information and belief, Padagis will thus contribute to the infringement of the '139 patent under 35 U.S.C. § 271(c).

151. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Padagis as to liability for the infringement of '139 patent claims. Padagis's actions have created in Plaintiff a reasonable apprehension of irreparable harm and loss resulting from Padagis's threatened imminent actions.

COUNT X
(Declaratory Judgment of Patent Infringement of the '516 Patent Under 35 U.S.C. § 271(a))

152. Plaintiff realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

153. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

154. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Padagis's ANDA Product, if approved by the FDA, will infringe literally and/or under the doctrine of equivalents one or more claims of the '516 patent under 35 U.S.C. § 271(a), in violation of Plaintiff's patent rights.

155. Upon information and belief, Padagis has knowledge of the '516 patent and has filed ANDA No. 217148 seeking authorization to commercially manufacture, use, offer for sale, and sell Padagis's ANDA Product in the United States. Upon information and belief, if the FDA approves ANDA No. 217148, physicians, health care providers, and/or patients will use Padagis's ANDA Product in accordance with the instructions and/or label provided by Padagis and will

directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '516 patent under 35 U.S.C. § 271(a), in violation of Plaintiff's patent rights.

156. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Padagis as to liability for the infringement of '516 patent claims. Padagis's actions have created in Plaintiff a reasonable apprehension of irreparable harm and loss resulting from Padagis's threatened imminent actions.

COUNT XI
(Declaratory Judgment of Patent Infringement of the '896 Patent Under 35 U.S.C. § 271(a), (b), and/or (c))

157. Plaintiff realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

158. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

159. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Padagis's ANDA Product, if approved by the FDA, will infringe literally and/or under the doctrine of equivalents one or more claims of the '896 patent under 35 U.S.C. § 271(a), in violation of Plaintiff's patent rights.

160. Upon information and belief, Padagis has knowledge of the '896 patent and has filed ANDA No. 217148 seeking authorization to commercially manufacture, use, offer for sale, and sell Padagis's ANDA Product in the United States. Upon information and belief, if the FDA approves ANDA No. 217148, physicians, health care providers, and/or patients will use Padagis's ANDA Product in accordance with the instructions and/or label provided by Padagis and will

directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '896 patent under 35 U.S.C. § 271(a), in violation of Plaintiff's patent rights.

161. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Padagis's ANDA Product so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '896 patent, including at least claim 49, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiff's patent rights.

162. Upon information and belief, Padagis knows and intends that physicians, health care providers, and/or patients will use Padagis's ANDA Product in accordance with the instructions and/or label provided by the '896 patent, including at least claim 49, with the requisite intent under 35 U.S.C. § 271(b).

163. Upon information and belief, if the FDA approves ANDA No. 217148, Padagis will sell or offer to sell Padagis's ANDA Product specifically labeled for use in practicing one or more claims of the '896 patent, including at least claim 49, wherein Padagis's ANDA Product is a material part of the invention claimed in the '896 patent, wherein Padagis knows that physicians will prescribe and patients will use Padagis's ANDA Product for practicing one or more claims in the '896 patent, and wherein Padagis's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Padagis will thus contribute to the infringement of the '896 patent under 35 U.S.C. § 271(c).

164. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Padagis as to liability for the infringement of '896 patent claims. Padagis's actions have created in Plaintiff a reasonable apprehension of irreparable harm and loss resulting from Padagis's threatened imminent actions.

COUNT XII
(Declaratory Judgment of Patent Infringement of the '700 Patent Under 35 U.S.C. § 271(a), (b), and/or (c))

165. Plaintiff realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

166. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

167. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Padagis's ANDA Product, if approved by the FDA, will infringe literally and/or under the doctrine of equivalents one or more claims of the '700 patent under 35 U.S.C. § 271(a), in violation of Plaintiff's patent rights.

168. Upon information and belief, Padagis has knowledge of the '700 patent and has filed ANDA No. 217148 seeking authorization to commercially manufacture, use, offer for sale, and sell Padagis's ANDA Product in the United States. Upon information and belief, if the FDA approves ANDA No. 217148, physicians, health care providers, and/or patients will use Padagis's ANDA Product in accordance with the instructions and/or label provided by Padagis and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '700 patent under 35 U.S.C. § 271(a), in violation of Plaintiff's patent rights.

169. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Padagis's ANDA Product so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '700 patent, including at least claim 59, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiff's patent rights.

170. Upon information and belief, Padagis knows and intends that physicians, health care providers, and/or patients will use Padagis's ANDA Product in accordance with the instructions and/or label provided by the '700 patent, including at least claim 59, with the requisite intent under 35 U.S.C. § 271(b).

171. Upon information and belief, if the FDA approves ANDA No. 217148, Padagis will sell or offer to sell Padagis's ANDA Product specifically labeled for use in practicing one or more claims of the '700 patent, including at least claim 59, wherein Padagis's ANDA Product is a material part of the invention claimed in the '700 patent, wherein Padagis knows that physicians will prescribe and patients will use Padagis's ANDA Product for practicing one or more claims in the '700 patent, and wherein Padagis's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Padagis will thus contribute to the infringement of the '700 patent under 35 U.S.C. § 271(c).

172. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Padagis as to liability for the infringement of '700 patent claims. Padagis's actions have created in Plaintiff a reasonable apprehension of irreparable harm and loss resulting from Padagis's threatened imminent actions.

COUNT XIII
(Declaratory Judgment of Patent Infringement of the '512 Patent Under 35 U.S.C. § 271(a), (b), and/or (c))

173. Plaintiff realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

174. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

175. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Padagis's ANDA Product, if approved by the FDA, will infringe literally and/or under the doctrine of equivalents one or more claims of the '512 patent under 35 U.S.C. § 271(a), in violation of Plaintiff's patent rights.

176. Upon information and belief, Padagis has knowledge of the '512 patent and has filed ANDA No. 217148 seeking authorization to commercially manufacture, use, offer for sale, and sell Padagis's ANDA Product in the United States. Upon information and belief, if the FDA approves ANDA No. 217148, physicians, health care providers, and/or patients will use Padagis's ANDA Product in accordance with the instructions and/or label provided by Padagis and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '512 patent under 35 U.S.C. § 271(a), in violation of Plaintiff's patent rights.

177. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Padagis's ANDA Product so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '512 patent, including at least claim 32, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiff's patent rights.

178. Upon information and belief, Padagis knows and intends that physicians, health care providers, and/or patients will use Padagis's ANDA Product in accordance with the instructions and/or label provided by the '512 patent, including at least claim 32, with the requisite intent under 35 U.S.C. § 271(b).

179. Upon information and belief, if the FDA approves ANDA No. 217148, Padagis will sell or offer to sell Padagis's ANDA Product specifically labeled for use in practicing one or more claims of the '512 patent, including at least claim 32, wherein Padagis's ANDA Product is a

material part of the invention claimed in the '512 patent, wherein Padagis knows that physicians will prescribe and patients will use Padagis's ANDA Product for practicing one or more claims in the '512 patent, and wherein Padagis's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Padagis will thus contribute to the infringement of the '700 patent under 35 U.S.C. § 271(c).

180. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Padagis as to liability for the infringement of '512 patent claims. Padagis's actions have created in Plaintiff a reasonable apprehension of irreparable harm and loss resulting from Padagis's threatened imminent actions.

COUNT XIV
(Declaratory Judgment of Patent Infringement of the '404 Patent Under 35 U.S.C. § 271(a))

181. Plaintiff realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

182. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

183. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Padagis's ANDA Product, if approved by the FDA, will infringe literally and/or under the doctrine of equivalents one or more claims of the '404 patent under 35 U.S.C. § 271(a), in violation of Plaintiff's patent rights.

184. Upon information and belief, Padagis has knowledge of the '404 patent and has filed ANDA No. 217148 seeking authorization to commercially manufacture, use, offer for sale, and sell Padagis's ANDA Product in the United States. Upon information and belief, if the FDA

approves ANDA No. 217148, physicians, health care providers, and/or patients will use Padagis's ANDA Product in accordance with the instructions and/or label provided by Padagis and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '404 patent under 35 U.S.C. § 271(a), in violation of Plaintiff's patent rights.

185. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Padagis as to liability for the infringement of '404 patent claims. Padagis's actions have created in Plaintiff a reasonable apprehension of irreparable harm and loss resulting from Padagis's threatened imminent actions.

COUNT XV
(Declaratory Judgment of Patent Infringement of the '186 Patent Under 35 U.S.C. § 271(b) and/or (c))

186. Plaintiff realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

187. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(b)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

188. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Padagis's ANDA Product so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '186 patent, including at least claim 1, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiff's patent rights.

189. Upon information and belief, Padagis knows and intends that physicians, health care providers, and/or patients will use Padagis's ANDA Product in accordance with the

instructions and/or label provided by the '186 patent, including at least claim 1, with the requisite intent under 35 U.S.C. § 271(b).

190. Upon information and belief, if the FDA approves ANDA No. 217148, Padagis will sell or offer to sell Padagis's ANDA Product specifically labeled for use in practicing one or more claims of the '186 patent, including at least claim 1, wherein Padagis's ANDA Product is a material part of the invention claimed in the '186 patent, wherein Padagis knows that physicians will prescribe and patients will use Padagis's ANDA Product for practicing one or more claims in the '186 patent, and wherein Padagis's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Padagis will thus contribute to the infringement of the '186 patent under 35 U.S.C. § 271(c).

191. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Padagis as to liability for the infringement of '186 patent claims. Padagis's actions have created in Plaintiff a reasonable apprehension of irreparable harm and loss resulting from Padagis's threatened imminent actions.

COUNT XVI
(Declaratory Judgment of Patent Infringement of the '101 Patent Under 35 U.S.C. § 271(b) and/or (c))

192. Plaintiff realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

193. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(b)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

194. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Padagis's ANDA Product so labeled, if

approved by the FDA, will induce and contribute to the infringement of one or more claims of the '101 patent, including at least claim 1, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiff's patent rights.

195. Upon information and belief, Padagis knows and intends that physicians, health care providers, and/or patients will use Padagis's ANDA Product in accordance with the instructions and/or label provided by the '101 patent, including at least claim 1, with the requisite intent under 35 U.S.C. § 271(b).

196. Upon information and belief, if the FDA approves ANDA No. 217148, Padagis will sell or offer to sell Padagis's ANDA Product specifically labeled for use in practicing one or more claims of the '101 patent, including at least claim 1, wherein Padagis's ANDA Product is a material part of the invention claimed in the '101 patent, wherein Padagis knows that physicians will prescribe and patients will use Padagis's ANDA Product for practicing one or more claims in the '101 patent, and wherein Padagis's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Padagis will thus contribute to the infringement of the '101 patent under 35 U.S.C. § 271(c).

197. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Padagis as to liability for the infringement of '101 patent claims. Padagis's actions have created in Plaintiff a reasonable apprehension of irreparable harm and loss resulting from Padagis's threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

(a) A judgment that Padagis has infringed the Asserted Patents and/or will infringe, actively induce infringement of, and/or contribute to infringement by others of the Asserted Patents;

(b) A judgment ordering that the effective date of any FDA approval for Padagis to make, use, offer for sale, sell, market, distribute, or import Padagis's ANDA Product, or any product the use of which infringes the Asserted Patents, be not earlier than the expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A permanent injunction enjoining Padagis, and all persons acting in concert with Padagis, from making, using, selling, offering for sale, marketing, distributing, or importing Padagis's ANDA Product, or any product the use of which infringes the Asserted Patents, or the inducement of or contribution to any of the foregoing, prior to the expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing of Padagis's ANDA Product, or any product the use of which infringes the Asserted Patents, prior to the expiration date of the Asserted Patents, infringes, will infringe, will actively induce infringement of, and/or will contribute to the infringement by others of the Asserted Patents;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiff's costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

/s/ Nathan R. Hoeschen

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Dated: May 2, 2022